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**TRANSMITTAL  
FORM**

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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/763,558	
	Filing Date	January 23, 2004	
	First Named Inventor	John E. Nash, et al.	
	Art Unit		
	Examiner Name		
Total Number of Pages in This Submission	8	Attorney Docket Number	K1008/20454

**ENCLOSURES (Check all that apply)**

<input type="checkbox"/> Fee Transmittal Form (In duplicate) <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53 <input type="checkbox"/> Assignment and Cover Sheet	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance communication to Technology Center (TC) <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Return Receipt Postcard, PTO Form 1449 and a copy of necessary references
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Firm or Individual name	Barry A. Stein, Esq.
Signature	
Date	April 12, 2004

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**PATENT**

**UNITED STATES PATENT AND TRADEMARK OFFICE  
PATENT EXAMINING OPERATION**

Applicants: John E. Nash, Douglas G. Evans and David M. Hoganson

Serial No: 10/763,558

Group Art Unit:

Filed: January 23, 2004

Examiner:

Att. Docket No.: K1008/20454

Confirmation No.:

For: **SYSTEMS AND METHODS FOR DELIVERING  
AGENTS INTO TARGETED TISSUE OF A LIVING BEING**

**INFORMATION DISCLOSURE STATEMENT**

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Sir:

Pursuant to 37 CFR §1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO-1449. Unless otherwise indicated herein, one copy of each reference is attached, except for U.S. Patents or U.S. published patent applications listed on the attached PTO-1449 Form as per the PTO waiver in 1276 OG 55. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom. No representation is made that the references are prior art with respect to this application.

Application No. 10/763,558  
IDS dated April 12, 2004

This Information Disclosure Statement is being filed within three months of the filing date of a national application other than a CPA under 37 CFR § 1.53(d), within three months of the date of entry of the national stage as set forth in 37 CFR § 1.491 in an international application, before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of an RCE under 37 CFR § 1.114. No certification or fee is required. 37 CFR § 1.97(b).

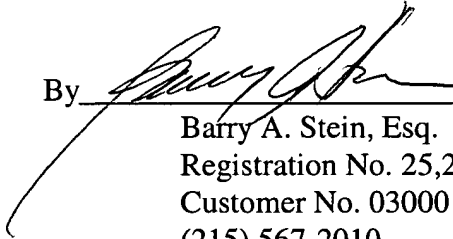
Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,  
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April 12, 2004

Please charge or credit our Account  
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By

  
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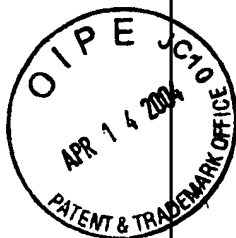
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Confirmation Number	
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First Named Inventor	John E. Nash et al.
Group Art Unit	
Examiner Name	
Attorney Docket Number	K1008/20454
Customer Number	03000

Sheet 1 of 5

## **U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code (if known)		
		1,902,418		Pilgrim	03/1933
		2,398,544		Lockart	04/1946
		2,737,946		Hein, Jr.	03/1956
		2,762,370		Venditty	09/1956
		2,800,903		Smoot	07/1957
		3,815,594		Doherty	06/1974
		3,887,699		Yolles	06/1974
		3,930,505		Wallach	01/1976
		4,165,739		Doherty et al.	08/1979
		4,315,742		Nash et al.	02/1982
		4,406,656		Hattler et al.	09/1983
		4,589,412		Kensey	05/1986
		4,631,052		Kensey	12/1986
		4,637,905		Gardner	01/1987
		4,652,441		Okada et al.	03/1987
		4,658,817		Hardy	04/1987
		4,664,112		Kensey et al.	05/1987
		4,679,558		Kensey et al.	07/1987
		4,686,982		Nash	08/1987
		4,690,672		Veltrup	09/1987
		4,700,705		Kensey et al.	10/1987
		4,747,406		Nash	05/1988
		4,747,821		Kensey et al.	05/1988
		4,749,376		Kensey et al.	06/1988
		4,790,813		Kensey	12/1988
		4,795,438		Kensey et al.	12/1988
		4,839,215		Starling et al.	06/1989
		4,900,303		Lemelson	02/1990
		4,994,033		Shockey et al.	02/1991
		5,021,044		Sharkawy	06/1991





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				Examiner Name	
				Attorney Docket Number	K1008/20454
				Customer Number	03000
Sheet	2	of	5		
<b>U.S. PATENT DOCUMENTS</b>					

	5,037,432	Molinari	08/1991
	5,042,984	Kensey et al.	08/1991
	5,087,244	Wolinsky et al.	02/1992
	5,112,305	Barath et al.	05/1992
	5,199,951	Spears	04/1993
	5,244,460	Unger et al	09/1993
	5,279,565	Klein et al.	01/1994
	5,288,502	McGinity et al.	02/1994
	5,415,636	Forman	05/1995
	5,415,637	Khosravi	05/1995
	5,456,667	Ham et al.	10/1995
	5,496,267	Drasler et al.	03/1996
	5,498,238	Shapland et al.	03/1996
	5,527,292	Adams et al.	06/1996
	5,591,159	Taheri	01/1997
	5,607,421	Jeevanandam et al.	03/1997
	5,655,548	Nelson et al.	08/1997
	5,674,197	van Muiden et al.	10/1997
	5,704,911	Parsons	01/1998
	5,718,921	Mathiowitz et al.	02/1998
	5,755,682	Knudson et al.	05/1998
	5,836,905	Lemelson et al.	11/1998
	5,810,836	Hussein et al.	08/1998
	5,840,059	March et al.	11/1998
	5,871,469	Eggers et al.	02/1999
	5,878,751	Hussein et al.	03/1999
	5,879,713	Roth et al.	03/1999
	5,893,840	Hull et al.	04/1999
	5,904,670	Schreiner	05/1999
	5,912,017	Mathiowitz et al.	06/1999
	5,925,016	Chornenky et al.	07/1999



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<b>U.S. PATENT DOCUMENTS</b>					

		5,935,119		Guy et al.	08/1999
		5,941,868		Kaplan et al.	08/1999
		5,997,525		March et al.	12/1999
		6,080,170		Nash et al.	06/2000
		6,261,585		Sefton et al.	07/2001

Examiner Initials*	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T
		Office	Number	Kind Code (If known)			
		EP	0 807 412	A1	United States Surgical Corporation	11/19/97	
		EP	0 876 803	A2	C.R. Bard, Inc.	11/11/98	
		EP	0 876 803	A3	C.R. Bard, Inc.	11/11/98	
		DE	296 19 029	U1	Kletke, Georg	11/02/96	
		WO	97/32551		Energy Life Systems Corporation	09/12/97	
		WO	98/19614		Fogarty, Thomas	05/14/98	
		WO	98/39038		Scimed Life Systems, Inc.	09/11/98	
		WO	98/49964		C.R. Bard, Inc.	11/12/98	
		WO	99/22655		Scimed Life Systems, Inc.	05/14/99	
		WO	99/22658		Scimed Life Systems, Inc.	05/14/99	
		WO	99/27985		Scimed Life Systems, Inc.	06/10/99	
		WO	99/33510		Hydrocision, Inc.	07/08/99	
		WO	99/44523		Scimed Life Systems, Inc.	09/10/99	
		WO	99/44524		Scimed Life Systems, Inc.	09/10/99	

**OTHER NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T
		Arras et al., The Delivery of Angiogenic Factors to the Heart by Microsphere Therapy, Nature Biotechnology, Volume 16, 159-162, February 1998;	
		Bonan, Raul, M.D., Local Drug Delivery for the Treatment of Thrombus and Restenosis, The Journal of Invasive Cardiology, 8:399-408, October 1996;	
		Edelman, et al., Basic Fibroblast Growth Factor Enhances The Coupling Of Intimal Hyperplasia And Proliferation Of Vasa Vasorum In Injured Rat Arteries, J. Chin Invest, Volume 89, February 1992, 465-473;	
		Edelman et al., Perivascular and Intravenous Administration Of Basic Fibroblast Growth Factor: Vascular And Solid Organ Deposition, Proc. Natl. Acad. Sci., USA, Vol. 90, 1513-1517, February 1993;	



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Sheet	4	of	5		
<b>U.S. PATENT DOCUMENTS</b>					

		Fasol et al., Experimental Use Of A Modified Fibrin Glue To Induce Site-Directed Angiogenesis From The Aorta To the Heart, The Journal of Thoracic and Cardiovascular Surgery, Volume 107, 1432-1439, June 1994;	
		Goldman et al., Experimental Method For Producing A Collageral Circulation To The Heart Directly Form The Left Ventricle, The Journal of Thoracic and Cardiovascular Surgery, 31:364-374, March, 1965;	
		Harada, et al., Basic Fibroblast Growth Factor Improves Myocardial Function In Chronically Ischemic Porcine Hearts, J. Chin. Invest, Volume 94, August 1994, 623-630;	
		Kimura et al., Cellular Response In Subretinal Neovascularization Induced by bFGF-Impregnated Microspheres, IOVS, February, 1999, Vol. 40, 524-528;	
		Krabatash et al., Histological Findings After Transmyocardial Laser Revascularization, The Journal of Cardiac Surgery, 11:326-331, 1996;	
		Lopez, et al., Basic Fibroblast Growth Factor in a Porcine Model of Chronic Myocardial Ischemia: A comparison of Angiographic, Echocardiographic and Coronary Flow Parameters. The Journal of Pharmacology and Experimental Therapeutics, Vol. 282, No. 1, pgs. 385-390, 1997;	
		Mack et al., Biologic Bypass with the Use of Andenovirus-Mediated Gene Transfer of the Complementary Deoxyribonucleic Acid for Vascular Endothelial Growth Factor 121 Improves Myocardial Perfusion and Function in the Ischemic Porcine Heart, The Journal of Thoracic and Cardiovascular Surgery, 115:168-177, January 1998;	
		Massimo et al., Myocardial Revascularization By A New Method Of Carrying Blood Directly From The Left Ventricular Cavity Into The Coronary Circulation, J. Thorac, Surg., 34:257-264, August, 1957;	
		Mirhoseini, et al., New Concepts in Revascularization of the Myocardium, Ann. Tho. Surg., 45:415-420, April 1988;	
		Moosdorf, et al., Transmyocardial Laser Revascularization-Morphologic Pathophysiologic and Historical Principles of Indirect Revascularization of The Heart Muscle, Z Kardiol, 86(3): 147-164, March, 1997;	
		Nishi et al., Basic Fibroblast Growth Factor Impregnated Hydrogel Microspheres For Embolization of Cerebral Arteriovenous Malformations, ASAIO Journal, 1998, M405-M410;	
		Pelletier, et al., Angiogenesis and Growth Factor Expression in a Model of Transmyocardial Revascularization, Annals of Thoracic Surgery, 66:12-18, 1998;	
		Pifarre, et al., Myocardial Revascularization by Transmyocardial Acupuncture, A Physiologic Impossibility, The Journal of Thoracic and Cardiovascular Surgery, 58:424-431, September 1969;	
		Sanborn, et al., Abstract of Percutaneous Endocardial Gene Therapy In Vivo Gene Transfer and Expression, The Journal of the American College of Cardiology, 33:262A, February 1999;	



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PTO/SB/08A (08-00)

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Sheet	5	of	5		
<b>U.S. PATENT DOCUMENTS</b>					

		Sellke et al., Basic FGF Enhances Endothelium-Dependent Relaxation of the Collateral Perfused Coronary Microcirculation. The American Physiological Society, 1994, pgs. H1303-H1311;	
		Sellke et al., Therapeutic Angiogenesis With Basic Fibroblast Growth Factor: Technique and Early Results, Ann Thorac, Surg., 1540-1544, 1998;	
		Sen et al., Transmyocardial Acupuncture: A New Approach to Myocardial Revascularization, Journal of Thoracic and Cardiovascular Surgery, 50:181-187, August, 1965;	
		Tabata et al., In Vitro Sorption and Desorption of Basic Fibroblast Growth Factor From Biodegradable Hydrogels, Biomaterials 19 (1998) 1781-1789;	
		Taguchi et al., Preparation of a Novel Functional Hydrogel Consisting Of Sulfated Glucoside-bearing Polymer: Activation Of Basic Fibroblast Growth Factor, 386-391;	
		Uchida et al., Angiogenic Therapy of Acute Myocardial Infarction by Intrapericardial Injection of Basic Growth Factor and Heparin Sulfate: An Experimental Study, the American Heart Journal, 130:1182-1188, December 1995;	
		Wilensky et al., Direct Intraarterial Wall Injection Of Microparticles Via A Catheter: A Potential Drug Delivery Strategy Following Angioplasty, American Heart Journal, Volume 122, 1136-1140, October 1991;	
		Wintzer et al., Transmyocardial Laser Revascularization. Historical Features in Human Nonresponder Myocardium appearing in Circulation, 95(c): 371-375, January 21, 1997.	
<b>EXAMINER</b>		<b>DATE CONSIDERED</b>	
<p>*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>			